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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/753,116

01/07/2004

Michael J. Kubek

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03/12/2008

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EXAMINER

AZPURU, CARLOS A

ART UNIT

PAPER NUMBER

1615

MAIL DATE

DELIVERY MODE

03/12/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/753,116	Applicant(s) KUBEK, MICHAEL J.	
	Examiner Carlos A. Azpuru	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 December 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged off the declaration and remarks filed 12/10/2007.

Response to Amendment

The declaration under 37 CFR 1.132 filed 12/10/2007 is sufficient to overcome the rejection of claims 1-6 based upon Tice et al in view of EP'726.

While it has been noted that the various parent applications contained restriction requirements, the allowed claims are such that obvious-type double patenting rejections are required.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

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Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-6 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of U.S. Patent No. 6,303,134 (US'134). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'134 claims a method of selectively inhibiting release of an endogenous compound comprising selecting an in situ locus in the central nervous system and stereotaxically delivering to the in situ locus at least one biodegradable non spherical polymeric microstructure comprising a pharmaceutical carrier and an agonist wherein the microstructure has a size and shape sufficient to prevent dispersion from the locus. (see claim 1). Glutamate and TRH are specifically recited in claim 8 as the endogenous compound and agonist, respectively. The percentage of agonist is set out as between 1 and 90% in claim 17. Therefore while the instant claims seek to increase an endogenous compound, the method of making this change requires the same administration to a central nervous system locus with the same non-spherical microstructure. Those of ordinary skill would therefore expect either and increase or decrease in the endogenous compound given the claims of copending US'134. The instant claims would have therefore been obvious to one of ordinary skill at the time of filing given the claims of US'134.

Claims 1-4 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-14 of U.S. Patent No. 6,491,939 (US'939). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'939 claims a method of selectively increasing release of an endogenous compound comprising selecting an in situ locus in the central nervous system and stereotaxically delivering to the in situ locus at least one biodegradable non spherical polymeric microstructure comprising a pharmaceutical carrier and an agonist wherein the microstructure has a size and shape sufficient to prevent dispersion from the locus. (see claim 1). Neurotransmitters, neuropeptides and hormones are specifically recited in claim 4 as the endogenous compound. Therefore while the instant claims seek to increase an endogenous compound, the method of making this change requires the same administration to a central nervous system locus with the same non-spherical microstructure. Stereotaxic implantation and the use of a cannula is well known in the surgical arts. Those of ordinary skill would therefore expect either and increase in the endogenous compound given the claims of copending US'939. The instant claims would have therefore been obvious to one of ordinary skill at the time of filing given the claims of US'939.

Claims rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6,699,491 (US'491). Although the conflicting claims are not identical, they are not patentably distinct from each other because US'491 claims a method of selectively inhibiting release of an endogenous compound comprising selecting an in situ locus in the central nervous system and stereotaxically delivering to the in situ locus at least one biodegradable non spherical polymeric microstructure comprising a pharmaceutical carrier and an agonist wherein the microstructure has a size and shape sufficient to prevent dispersion from the locus. (see claim 1). TRH is specifically recited in claim 2 as the agonist. Therefore while the instant claims seek to increase an endogenous compound, the method of making this change requires the same administration to a central nervous system locus with the same non-spherical microstructure. Those of ordinary skill would therefore expect either an increase or decrease in the endogenous compound given the claims of copending US'491. The instant claims would have therefore been obvious to one of ordinary skill at the time of filing given the claims of US'491.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Carlos A. Azpuru/
Primary Examiner, Art Unit 1615

Carlos A. Azpuru
Primary Examiner
Art Unit 1615

CA

Art Unit: 1615